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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/111,123	07/06/98	ZAGHOUANI H	ALLIA143

HM12/1118

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EXAMINER	
NOLAN, P	
ART UNIT	**PAPER NUMBER**
1644	5

DATE MAILED: 11/18/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/111,123	Zaghouani
Examiner	**Group Art Unit**
NOLAN	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Peri d for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 10-21-99.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above claim(s) 8-20 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of References Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Other SEP LETTER

Office Action Summary

Part III DETAILED ACTION

1. Claims 1-20 are pending.

2. Applicant's election of Group I, claims 1-7 in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 8-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The declaration was not signed.

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

5. Claims 1-7 are rejected under 35 U.S.C. § 103 as being unpatentable over Bona et al. (U) in view of Liu et al., (V) and Karpus et al.,(W).

Bona et al., teaches a fusion protein comprising an IgG immunoglobulin with its CDR3 region replaced by a viral peptide, wherein said fusion protein is endocytosed by cells bearing an Fc receptor, processed by said cells and wherein said cell express said viral peptides, wherein said viral peptides are T cell peptides which specifically stimulate T cells (abstract, in particular).

The claimed invention differs from the prior art teachings by the recitations of using T cell receptor peptide agonists derived from proteolipid or myelin basic protein. However, Liu et al., teaches the induction of tolerance in EAE mice with the use of a peptide derived from MBP (abstract, in particular). Liu et al., also teaches that induction of tolerance with self-peptide takes time to develop (see abstract, in particular). Karpus et al., teaches the induction of tolerance in EAE mice with the use of a peptide from proteolipid,(see abstract, in particular). In addition Bona et al., teaches that using Immunoglobulins (IG's) replaced in the CDR3 region are useful in targeting antigens to antigen presenting cells because IG's have longer half lives than synthetic peptides, (page 23 in particular). Bona et al., also teaches that the method of delivering antigens to cells via IG's "can be extended to express other biologically important epitopes such as tumor antigens, oncogenes or self antigens which can be used in the antitumor therapy or the therapy of autoimmune diseases" (page 29, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to substitute viral peptide-IgG fusion proteins taught by Bona et al., for a T cell receptor agonist derived from proteolipid taught by Karpus et al., or from myelin basic protein, as taught by Liu et al., because peptide-IgG fusion proteins are better for delivery of antigens of interest because IG's have longer half lives than synthetic peptides as taught by Bona et al., and longer half life is necessary for tolerance induction to occur as taught by Liu et al., and because Karpus et al., and Liu et al., teach the successful use of a peptide agonist, for treating EAE, wherein said peptide is derived from proteolipid protein or myelin basic protein. In addition, it would have also been obvious to one of skill in the art to use both self-protein agonists, PLP and MBP, in a single fusion protein since both MBP and PLP are well known autoantigens for the same autoimmune disease EAE. Inducing tolerance in an animal to both known autoantigens for a specific autoimmune disease would have been obvious to one of skill in the art. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is prima

facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan, Ph.D.
Patent Examiner, Group 1640
November 17, 1999